UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

A.F. OF L. – A.G.C. BUILDING TRADES WELFARE PLAN, individually and on behalf of itself and all others similarly situated, Plaintiff, v. JAZZ PHARMACEUTICALS PLC; ROXANE LABORATORIES, INC.; WEST-WARD PHARMACEUTICALS CORP.; HIKMA LABS INC.; HIKMA PHARMACEUTICALS USA INC.; HIKMA PHARMACEUTICALS PLC; AMNEAL PHARMACEUTICALS LLC; PAR PHARMACEUTICAL, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS INC.; and LUPIN INC., Defendants.	Civil Action No. **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan ("Plaintiff"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Defendants Jazz Pharmaceuticals plc ("Jazz"); Roxane Laboratories, Inc. ("Roxane"); West-Ward Pharmaceuticals Corp. ("West-Ward"); Hikma Pharmaceuticals USA Inc. (f/k/a West-Ward Pharmaceuticals Corp.); Hikma Labs Inc.; Hikma Pharmaceuticals plc (collectively, "Hikma"); Amneal Pharmaceuticals LLC ("Amneal"); Par Pharmaceutical, Inc. ("Par"); Lupin Ltd.; Lupin Pharmaceuticals Inc.; and Lupin Inc. (collectively "Lupin"), for Defendants' violations of federal antitrust law and state antitrust, consumer protection, and unjust enrichment laws concerning the narcolepsy drug Xyrem (sodium oxybate). Based on personal knowledge, information and belief, and the investigation of counsel, Plaintiff alleges as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of Defendants' anticompetitive conduct that delayed generic competition in the United States and its territories for Xyrem, a prescription drug product approved by the U.S. Food and Drug Administration (the "FDA") in the United States for treatment of cataplexy and daytime sleepiness in patients with narcolepsy. Plaintiff seeks overcharge damages arising from Defendants' unlawful and anticompetitive tactics to maintain a monopoly in the market for sodium oxybate in the United States,[1] including, *inter alia*, obtaining invalid and unenforceable patents and improperly listing these patents in the FDA's Orange Book; prosecuting sham litigation based on fraudulent, invalid, or unenforceable patents; and settling that litigation with payments in exchange for promises to delay generic entry from drug manufacturers Roxane, Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt (collectively, the "Generic Manufacturers").

2. Defendants' anticompetitive behavior prevented, delayed, and restricted competition in the market for Xyrem and AB-rated generic versions ("generic versions") thereof in the United States. As a result, no generic version of Xyrem has entered the market and full generic competition will not occur until December 31, 2025 at the earliest.

3. The active ingredient in Xyrem is sodium oxybate, which is the sodium salt of gamma-hydroxybutyric acid (GHB), and acts as a central nervous system (CNS) depressant.

4. Xyrem was developed by Orphan Medical ("Orphan"), approved by the FDA in 2002 for the treatment of cataplexy and excessive daytime sleepiness associated with narcolepsy,

[1] "United States" is defined herein to include the United States, its territories, possessions, and the Commonwealth of Puerto Rico.

and launched that year. Jazz acquired Orphan in 2005, and Xyrem quickly became Jazz's signature drug, accounting for approximately 72% of its revenues by 2007.

5. Since 2007, Jazz has incrementally raised the price of Xyrem from $2.04 per milliliter to $29.69, an increase of over 1,350%. For a patient taking a dosage in the middle of the effective range, the monthly cost of Xyrem exceeds $13,000.[2]

6. Net sales of Xyrem were $1.64 billion in 2019, representing 76% of Jazz's total revenue for that year.[3]

7. Defendant Roxane was the first generic manufacturer to file an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to manufacture, market, and sell a generic version of Xyrem including a certification that Jazz's patents covering Xyrem were invalid, unenforceable, and/or would not be infringed by the generic. Roxane was therefore entitled to 180 days of exclusivity under the Hatch-Waxman Act[4] before other generics could enter the market.

8. This exclusivity period was potentially worth hundreds of millions of dollars to Roxane,[5] giving the company a strong incentive to bring its generic to market as soon as possible. To avoid that outcome, which would be catastrophic for Jazz's bottom line, Jazz came to an agreement with Roxane whereby Roxane would delay launching its generic until at least July 1, 2023. In exchange for that promise, Jazz granted Roxane the exclusive license to sell an authorized

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[2] *See Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/xyrem (last updated May 4, 2020); *Xyrem Dosage,* Drugs.com, https://www.drugs.com/dosage/xyrem.html (last updated May 4, 2020) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

[3] Jazz Pharmaceuticals plc, Annual Report (Form 10-K) at 63 (Feb 25, 2020).

[4] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). *See infra* Section IV for a detailed explanation of the regulatory structure put in place by the Hatch-Waxman Act.

[5] *See FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) ("[The] 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars.").

generic (AG)[6] for six months beginning January 1, 2023, and the exclusive license to sell its own generic from July 1, 2023 until December 31, 2025. These promises were executed in the form of a settlement resolving patent litigation between Jazz and Roxane.

9. In effect, Jazz persuaded Roxane to give up its potential windfall from the six-month exclusivity period in the short term by promising to ensure Roxane enjoyed a longer, eighteen-month exclusivity period down the road.

10. Jazz kept its promises in a series of subsequent settlements of patent litigations with the other Generic Manufacturers who had submitted ANDAs. Since the other Generic Manufacturers were not entitled to the 180-day exclusivity period, the price to keep them off the market was much lower. By, *inter alia,* offering to share profits from a series of authorized generics with these generic manufacturers, Jazz secured promises from each of them not to launch their own generics until December 25, 2025.

11. The settlements with Roxane and the other Generic Manufacturers effectively allocated the market for sodium oxybate in the United States according to the following schedule:

- Branded Xyrem will maintain its monopoly until December 31, 2022;
- On January 1, 2023, Jazz will introduce an AG, and profits from the AG will be shared with Roxane;
- On July 1, 2023, Jazz will introduce several more AGs, and profits from those AGs will be shared with other generic manufacturers in accordance their respective patent litigation settlement agreements;
- Roxane may also launch its own generic on July 1, 2023;
- On December 31, 2025, Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt may launch their own generics.

[6] An authorized generic, or "AG," is simply the brand product, sold or licensed by the brand for sale, under generic trade dress, at a lower price. *See* FDA, *List of Authorized Generic Drugs* (Apr. 1, 2020), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs.

As a result of the Settlement Agreements, Jazz will maintain complete control of the sodium oxybate market in the United States until at least July 1, 2023, and full generic competition will not occur until at least December 31, 2025.

12. Plaintiff and the Class (defined below) have been injured by Defendants' anticompetitive conduct in the form of overcharges paid for branded Xyrem. In the absence of such anticompetitive conduct, Class members would have been able to buy less-expensive generic sodium oxybate in lieu of branded Xyrem as early as 2017.

II. JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs, there are more than one hundred Class members, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants. This Court also has jurisdiction under Section 16 of the Clayton Act, 15 U.S.C. § 26, and Sections 1 and 2 of the Sherman Act 15 U.S.C. §§ 1, 2.

14. Venue is appropriate within this district under 28 U.S.C. § 1391 because, at all relevant times, Defendants transacted business within this district, and the interstate trade and commerce described hereinafter is carried out, in substantial part, in this district. Venue is also appropriate under Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendant Par maintains an office in this district. Further, Defendants and/or their agents may be found in this district.

15. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury

to persons residing in, located in, or doing business throughout the United States, including in this district.

III. INTRADISTRICT ASSIGNMENT

16. Assignment to any division in this District is proper because the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried out within each division.

IV. THE PARTIES

17. Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan (the "A.F.L. Plan" or "Plaintiff") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The A.F.L. Plan purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs. The A.F.L. Plan represents participants who purchased and/or were provided reimbursement for some or all of the purchase price of Xyrem. The A.F.L. Plan purchased, paid and/or provided reimbursement for Xyrem in Alabama. The A.F.L. Plan paid more for Xyrem than it would have paid absent Defendants' unlawful anticompetitive conduct to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. The A.F.L. Plan intends to continue purchasing Xyrem and will be injured in the future.

18. Defendant Jazz Pharmaceuticals PLC ("Jazz") is a company organized under the laws of Ireland with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin L2 4, Ireland. Jazz maintains offices in California, Pennsylvania, and New Jersey. During all relevant times, Jazz was engaged in the development, manufacture, marketing, and sale of branded pharmaceutical products in the United States.

19. Defendant Roxane Laboratories, Inc. is corporation organized under the laws of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228. In 2016, Roxane Laboratories, Inc. was acquired by Defendant Hikma Pharmaceuticals PLC.

Between 2016 and 2018 the company operated under the name of Defendant West-Ward Pharmaceuticals Corp., a subsidiary of Hikma Pharmaceuticals PLC. Since 2018, the company has operated under the name of Defendant Hikma Pharmaceuticals USA, Inc. The term "Roxane" used hereinafter refers to the companies named in this paragraph, and the Hikma Defendants, collectively. During all relevant times, Roxane was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

20. Defendant Hikma Labs Inc. is a corporate organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228. During all relevant times, Hikma Labs Inc. was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

21. Defendant Hikma Pharmaceuticals plc is a public limited company organized and existing under the laws of the United Kingdom, with its principal place of business at 1 New Burlington Place, London, W1S 2HR and its U.S. headquarters at 246 Industrial Way West, Eatontown, New Jersey, 07724. During all relevant times, Hikma Pharmaceuticals plc was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

22. Defendant Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 246 Industrial Way West, Eatontown, New Jersey, 07724. It is a wholly-owned subsidiary of Hikma Pharmaceuticals plc. Prior to June 20, 2018, Hikma Pharmaceuticals USA Inc. was organized under the name West-Ward Pharmaceuticals Corp., which was acquired by Hikma Pharmaceuticals plc in 1998. During all relevant times, Hikma Pharmaceuticals USA Inc. was

engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

23. Defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey, 08807. During all relevant times, Amneal Pharmaceuticals LLC was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

24. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Ram Ridge Rd., Chestnut Ridge, New York, 10977. Par is a subsidiary of Endo International plc, an Irish public limited company with its U.S. headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. As used in this complaint, "Par" encompasses relevant predecessors-and-successors-in-interest. During all relevant times, Par Pharmaceutical, Inc. was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

25. Defendant Lupin Ltd. is a public limited company organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India. During all relevant times, Lupin Ltd. was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

26. Defendant Lupin Pharmaceuticals Inc., a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland, 21202. During all relevant

times, Lupin Pharmaceuticals Inc. was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

27. Defendant Lupin Inc., a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland, 21202. During all relevant times, Lupin Inc. was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

28. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with Defendants' actual and/or apparent authority.

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Drugs

29. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a company seeking to market a new drug must obtain the approval of the FDA by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-92. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

30. When the FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization

prior to the expiration of the listed patent(s). Relevant patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1), (c)(2).

31. The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or trustworthiness whether those patents are valid and enforceable, and actually cover the drug product or its use. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

32. In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA to expedite the entry of less expensive generic competitors to brand drugs to reduce healthcare expenses nationwide, while also providing for patent term extensions and the ability to file pre-launch infringement suits to bolster pharmaceutical companies' financial incentives to create new and innovative products. *See generally* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

33. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic revenues and profits for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did.[7] In 1985, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2018, total prescription drug revenue had climbed to more than $344 billion, with generic drugs accounting

[7] Congressional Budget Office, How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 37 (July 1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

for 90% of prescriptions.[8] Generics are now dispensed 97% of the time when a generic form is available.[9]

34. The Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA applicant must further show that the generic drug is bioequivalent (*i.e.*, that the active ingredient of the proposed generic drug is absorbed in the patient's blood stream to the same extent and for the same amount of time as the brand counterpart, 21 U.S.C. § 355(j)(8)(B)), and that it is pharmaceutically equivalent (*e.g.*, that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug). Generic drugs that are both bioequivalent and pharmaceutically equivalent are considered "therapeutically equivalent" to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq.*

35. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that therapeutically equivalent drugs are substitutable. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, a designation which causes a pharmacy presented with a prescription for the brand to automatically dispense the generic instead.

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[8] *See* IQVIA Institute, Medicine Use and Spending in the U.S. 2, 5 (May 2019), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1591811126454.

[9] *Id.; see also* IMS Institute for Healthcare Informatics, Medicine Use and Shifting Costs of Healthcare 30, 51 (Apr. 2014), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf.

2. Paragraph IV Certifications

36. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

(i) that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

(ii) that the patent for the brand drug has expired (a "Paragraph II certification");

(iii) that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

(iv) that the patent for the brand drug is invalid, unenforceable, and/or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

37. To obtain FDA approval of an ANDA prior to the expiration of a patent or patents listed in the Orange Book, a generic manufacturer must file a Paragraph IV certification and serve timely notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement pursuant to 35 U.S.C. § 271(e)(2). If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may grant tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the existence of an unexpired patent for which the generic filer has submitted a Paragraph III certification (*i.e.*, that the generic does not intend to market the ANDA product prior to the expiration of the patent) or the existence of a regulatory exclusivity, such as the 30-month stay.

3. First-Filer's 180-Day Exclusivity Period

38. Generics may be classified as (1) first-filer generics, (2) later-filing generics, or (3) the brand's own authorized generic.

39. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other later-filing generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that at least one unexpired patent listed in the Orange Book as covering the brand product is either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later-filing generic company's ANDA until that first-filer generic has been on the market for 180-days, or until the first-filer's 180-day exclusivity has been forfeited. The 180-day window is referred to as the first-filer's 180-day "exclusivity" or "exclusivity period."

40. By contrast, a first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product (*e.g.*, one that files a Paragraph III certification as to all Orange Book-listed patents) will not receive a 180-day exclusivity period. Congress created the 180-day exclusivity period to incentivize generic manufacturers to file Paragraph IV certifications challenging weak patents, or to invent around such patents by creating non-infringing generics.

41. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer.[10]

[10] *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) (internal citation and quotation marks omitted).

42. An authorized generic, or AG, is simply the brand product, sold or licensed by the brand for sale, under generic trade dress, at a less expensive price than the brand price. Because the AG is already approved under the brand manufacturer's NDA, it can be marketed at any time, including during the first-filer's 180-day exclusivity period.[11]

43. A brand can also license a first-filer generic competitor to launch an authorized generic. The first-filer's launch of an authorized generic triggers its 180-day exclusivity period.

B. The Benefits of AB-Rated Generic Competition

44. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market for a given brand.

45. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

46. The Federal Trade Commission ("FTC") found that by 12 months after generic entry, generics on average capture 90% of corresponding brand drug sales and (with multiple

[11] *See, e.g.*, FDA, Guidance for Industry, 180-Day Exclusivity: Questions and Answers at 13, https://www.fda.gov/media/102650/download.

generics on the market) prices drop 85% relative to brand prices.[12] That is because, once multiple generic competitors enter, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share by driving prices further down toward marginal manufacturing costs.[13] As a result, competition from generic drugs is viewed by brand drug companies, such as Jazz, as a grave financial threat.

47. By contrast, generic competition enables purchasers (like Class members here) to purchase substantially less expensive generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as more generic versions of that brand drug enter the market. In addition, generic competition enables purchasers to pay lower prices for their remaining brand companies when the brand company lowers its brand price to compete with the generic for sales.

48. Once exclusivity is lost and generic entry occurs—an event sometimes referred to as the "patent cliff"—the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics."[14]

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[12] *See* FTC, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions at 8 (Jan. 2010) ("FTC Pay-for-Delay Study"), http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[13] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & Econ. 311, 314, 339-41, 354-55 (2000).

[14] *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny.

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

49. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Jazz, are well aware of generics' rapid erosion of their brand sales, and thus seek to delay and stall the impact of generic competition for as long as possible, sometimes (as here) resorting to illegal means.

50. One way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes referred to as or "pay-for-delay agreements," and they have long concerned the FTC. Brand and generic manufacturers execute pay-for-delay agreements to take advantage of the regulatory consequences associated with the generic manufacturers' Paragraph IV certifications.

51. In a typical pay-for-delay agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product. Because of the sharp price drop that would result from generic competition, both the brand and the generic manufacturer can make more money from this arrangement than from competing against each other for increasingly smaller margins.

52. Pay-for-delay agreements often take the form of settlement agreements to end patent infringement suits filed by brand manufacturers when they get notice of an ANDA with a Paragraph IV certification concerning one or more of their patents. Instead of defending their patents in court, as the Hatch-Waxman Act's drafters intended, the brand company pays the generic manufacturer to stay off of the market, allowing both companies to benefit from monopoly profits.

These agreements are also called "reverse payment agreement," because the plaintiff pays the defendant to end the suit—the opposite of what normally happens in a civil settlement.

D. Pay-for-Delay Agreements with First-Filers Can Create Bottlenecks for Later-Filing Generics

53. An anticompetitive agreement entered into between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

54. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

55. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

56. However, later ANDA filers cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

57. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more-expensive brand drug instead.

VI. FACTUAL ALLEGATIONS

A. The History of GHB

58. GHB, the active ingredient in Xyrem, was discovered in 1960 by Henri Laborit, a French surgeon and neurobiologist, while he was searching for therapeutically useful analogues of gamma-aminobutyric acid (GABA), a naturally occurring inhibitory neurotransmitter. It was later discovered that GHB is itself a naturally-occurring substance found in brain and other tissues in the human body.

59. After his discovery, Laborit outlined the potential merits of GHB as an anesthetic agent. He further suggested GHB could have beneficial effects in obstetrics, psychiatry, alcohol and opiate withdrawal symptoms, and lipid metabolism.[15] Although GHB has been used as a surgical anesthetic in Europe, due to certain drawbacks it never gained wide acceptance as a general anesthetic.

60. After further investigations indicated that when taken at bedtime, GHB did not significantly change the normal sleep cycle, scientists recognized its potential to treat disorders that cause disruption in nocturnal sleep, such as narcolepsy. Initial clinical studies yielded promising results, demonstrating prompt improvements in the quality of nocturnal sleep in narcoleptic patients, and gradual abatement of the daytime symptoms of narcolepsy. [16]

61. During the 1980's, GHB was marketed in the U.S as an unregulated dietary supplement. Often used by body builders, it was thought to cause anabolic benefits by stimulating growth hormone release. It was also promoted as a 'natural' treatment for insomnia.[17]

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[15] *See* Henri Laborit *Sodium 4-hydroxybutyrate*, 3 Int'l J. Neuropharmacology 433 (1964).

[16] *See, e.g.*, Roger Broughton & Mortimer Mamelak, *The Treatment of Narcolepsy-Cataplexy with Nocturnal Gamma-Hydroxybutyrate,* 6 Can. J. of Neurological Sci. 1 (1979).

[17] *See* Gregory Wedin et al., *The Clinical Development of γ-Hydroxybutyrate (GHB)*, 1 Current Drug Safety 99 (2006).

62. Following reports of several fatal overdoses among body builders, the FDA banned all GHB sales in 1990.[18] After the FDA ban, GHB synthesis went underground but the drug was still widely available on the black market.

63. By the mid-1990's, illicit GHB was gaining notoriety as a popular club drug, with users reporting feelings of euphoria, disinhibition, and sexual arousal, similar to those caused by alcohol but without the unpleasant hangovers. Like many CNS depressants, GHB can also cause anterograde amnesia, especially when combined with alcohol, which led in part to its increasing use as a date-rape drug. GHB is still widely available on the black market and remains a popular club drug. Its use as a date-rape drug also continues.

B. Orphan Develops Xyrem

64. Based on the promising results of the initial investigations into GHB as treatment for narcolepsy, Orphan began formal clinical development of the drug (now known by its formal generic name: sodium oxybate) in 1994.

65. In 2000, Congress enacted the J. Farias and Samantha Reid Date-Rape Drug Prohibition Act.[19] The law proscribed a novel bifurcated scheduling of GHB under the Controlled Substances Act,[20] whereby GHB was listed as a Schedule I drug but with an exception that any FDA-approved formulations of the drug would be listed as Schedule III, thereby allowing Orphan to continue its clinical development.[21]

[18] *Id.* at 100.

[19] Public Law 106-172, 114 Stat. 7 (2000) (codified at 21 U.S.C. §§ 801, 802, 827, 841, 960).

[20] *Id.* at 8-9.

[21] *See* Wedin et al., *supra* note 17, at 101.

66. Orphan conducted a series of three clinical studies to establish the safety and efficacy of sodium oxybate as a treatment for narcolepsy,[22] the results of which reinforced the promise demonstrated in the earlier studies.

67. Orphan submitted an NDA for sodium oxybate under the brand name Xyrem on October 2000 and was granted approval on July 17, 2002 to market the drug for treatment of cataplexy associated with narcolepsy.

68. Jazz acquired Orphan 2005, and quickly made Xyrem its signature drug, recognizing its potential as a blockbuster.

C. Jazz Raises the Price of Xyrem by 1,355%

69. Since 2007, Jazz has incrementally raised the price of Xyrem from $2.04 per milliliter[23] to $29.69,[24] an increase of over 1,355%. For a patient taking a dosage in the middle of the effective range, the monthly cost of Xyrem is approximately $13,360.[25]

70. Net sales of Xyrem were $1.64 billion in 2019, representing 76% of Jazz's total revenue for that year.[26] The company's gross margin as a percent of net product sales was 94% in 2019.[27]

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[22] *See* The U.S. Xyrem® Multicenter Study Group, *A Randomized, Double Blind, Placebo-Controlled Multicenter Trial Comparing the Effects of Three Doses of Orally Administered Sodium Oxybate with Placebo for the Treatment of Narcolepsy*, 25 Sleep 42 (2002); U.S. Xyrem® Multicenter Study Group, *A 12-Month, Open-Label, Multicenter Extension Trial of Orally Administered Sodium Oxybate for the Treatment of Narcolepsy*, 1 Sleep 31 (2003); Xyrem® Multicenter Study Group, *Sodium Oxybate Demonstrates Long-Term Efficacy for The Treatment of Cataplexy in Patients with Narcolepsy*. 5 Sleep Med. 119 (2004).

[23] *See* Sean Williams, *A company's 841% price increase on a sleep drug could attract attention from Capitol Hill,* Business Insider (Nov. 2, 2016), https://www.businessinsider.com/jazz-drug-price-increase-841-percent-drug-regulators-2016-11.

[24] *See Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/xyrem (last updated May 4, 2020).

[25] *Xyrem Dosage,* Drugs.com, https://www.drugs.com/dosage/xyrem.html (last updated May 4, 2020) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

[26] Jazz Pharmaceuticals plc, Annual Report (Form 10-K) at 63 (Feb 25, 2020).

[27] *Id.* at 64.

D. Jazz's Xyrem Patents

71. Jazz is the holder of NDA No. 21-196/S-19, under which the FDA granted approval for a sodium oxybate oral solution to treat cataplexy and excessive daytime sleepiness in patients with narcolepsy. Jazz markets sodium oxybate in the United States under the trademark Xyrem®.

72. Jazz is the owner of U.S. Patent Nos. 6,472,431 (the '431 patent); 6,780,889 (the '889 patent); 7,262,219 (the '219 patent); 7,851,506 (the '506 patent); 8,263,650 (the '650 patent); 8,324,275 (the '275 patent); 8,859,619 (the '619 patent); 8,952,062 (the '062 patent) (collectively, "the '431 family"). All the patents in the '431 family are divisionals or continuations of the original application which resulted in '431 patent, and all cover a chemically stable formulation of GHB which is resistant to microbial growth.

73. Jazz is also the owner of U.S. Patents Nos. 7,668,730 (the '730 patent); 7,765,106 (the '106 patent); 7,765,107 (the '107 patent); 7,895,059 (the '059 patent); 8,457,988 (the '988 patent); 8,589,182 (the '182 patent); 8,731,963 (the '963 patent) (collectively, "the '730 family"). All the patents in the '730 family are divisionals or continuations of the application which resulted in '730 patent, and all cover a sensitive drug distribution system designed to satisfy the FDA's REMS program.

74. Jazz is also the owner of U.S. Patents Nos. 8,772,306 (the '306 patent); 9,050,302 (the '302 patent); 9,486,426 (the '426 patent) (collectively, "the '306 family"). All the patents in the '306 family are divisionals or continuations of the application which resulted in the '306 patent, and all cover a method of administrating GHB in patients using other CNS depressants.

75. Jazz's Xyrem patents and the anticipated expiration dates for each are represented in the Table 1, below:

Table 1

Patent	Type	Expiration Date	Family
6,472,431 (the '431 patent)	Original	December 22, 2019	431
6,780,889 (the '889 patent)	Divisional	July 4, 2020	431
7,262,219 (the '219 patent)	Divisional	April 5, 2021	431
7,851,506 (the '506 patent)	Divisional	December 22, 2019	431
8,263,650 (the '650 patent)	Continuation	December 22, 2019	431
8,324,275 (the '275 patent)	Continuation	December 22, 2019	431
8,859,619 (the '619 patent)	Continuation	December 22, 2019	431
8,952,062 (the '062 patent)	Continuation	December 22, 2019	431
7,668,730 (the '730 patent)	Original	June 16, 2024	730
7,765,106 (the '106 patent)	Divisional	June 19, 2027	730
7,765,107 (the '107 patent)	Divisional	September 19, 2026	730
7,895,059 (the '059 patent)	Continuation	December 17, 2022	730
8,457,988 (the '988 patent)	Divisional	December 17, 2022	730
8,589,182 (the '182 patent)	Continuation	December 17, 2022	730
8,731,963 (the '963 patent)	Continuation	December 17, 2022	730
8,772,306 (the '306 patent)	Original	March 15, 2033	306
9,050,302 (the '302 patent)	Continuation	March 15, 2033	306
9,486,426 (the '426 patent)	Continuation	March 15, 2033	306

E. The '730 Family Patents Were Invalidated by the PTAB

76. On or about January 8, 2015, Amneal and Par jointly filed a series of petitions before the Patent Trial and Appeal Board (PTAB) requesting institution of *inter partes* review (IPR) of the patents in the '730 family including the '730 patent (IPR2015-00554); the '106 patent (IPR2015-00546); the '107 patent (IPR2015-00547); the '059 patent (IPR2015-00548); the '988 patent (IPR2015-00551); and the '182 patent (IPR2015-00545). On or about September 14, 2015, Amneal and Par jointly filed a petition for *inter partes* review of the '963 Patent (IPR2015-01903).

77. The PTAB instituted *inter partes* review of the '182 patent (IPR2015-00545), the '106 patent (IPR2015-00546), '107 patent (IPR2015-00547), the '059 patent (IPR2015-00548), the '988 patent (IPR2015-00551), and the '730 patent (IPR2015-00554) on or about July 28, 2015, and did the same for the '963 patent (IPR2015-01903) on or about March 25, 2016

78. On July 27, 2016, the PTAB issued final decisions as to the '182 patent (IPR2015-00545), the '106 patent (IPR2015-00546), '107 patent (IPR2015-00547), the '059 patent (IPR2015-00548), the '988 patent (IPR2015-00551), and the '730 patent (IPR2015-00554), finding certain claims contained in each to be obvious and therefore unpatentable in light of prior art that was publicly available more than one year before patents' respective earliest priority filing dates.

79. On March 22, 2017, the PTAB issued a final decision as to the '963 patent (IPR2015-01903) finding certain claims to be obvious and therefore unpatentable in light of prior art that was publicly available more than one year before patent's earliest priority filing date.

80. The prior art came in the form of published and publicly available background materials to an FDA advisory committee meeting in June 2001, which describe in detail the REMS system that Jazz later patented under the '730 family. The earliest effective date for the '730 family patents is December 17, 2002, more than a year after the date the prior art became available publicly.

81. After Jazz appealed all seven decisions, the U.S. Court of Appeals for the Federal Circuit affirmed the PTAB in all instances.[28]

82. The result of *inter partes* review, as affirmed by the Federal Circuit, was the invalidation of all the patents in the '730 family.

F. The '306 Family Patents Were Obtained and Upheld as a Result of Defendants' Fraudulent Withholding of Prior Art

83. On or about March 1, 2013 Jazz filed a provisional application (No. 61/771,557) seeking patent protection for inventing a method of co-administering Xyrem in patients also taking

[28] *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1363 (Fed. Cir. 2018).

valproate—anther CNS depressant used to treat epilepsy, bipolar disorder, and migraine headaches—by administering a lower dose of Xyrem.

84. Provisional Application No. 61/771,557 resulted in three patents: 8,772,306 (the '306 patent); 9,050,302 (the '302 patent); and 9,486,426 (the '426 patent) (collectively, "the '306 family"). The earliest effective filing date for each patent in the '306 family is March 1, 2013.

85. In or around December 2012, Jazz published a revised version of its Xyrem label, updating the language regarding coadministration of Xyrem with other CNS depressants as reflected below:

Jazz's 2002 and 2005 Xyrem Labels	Jazz's 2012 Xyrem Label
"Sodium oxybate should not be used in combination with . . . other CNS depressants."[29]	"The concurrent use of Xyrem with other CNS depressants . . . may increase [certain risks]. If use of these CNS depressants in combination with Xyrem is required, dose reduction or discontinuation of one or more CNS depressants (including Xyrem) should be considered."[30]

86. During the prosecution of the `306 patents, Jazz disclosed to the PTO only its 2002 and 2005 labels, but withheld its 2012 revision.

87. Jazz's omissions persisted for over three-and-a-half years—over two years for the '302 patent (filed March 15, 2013, and issued June 9, 2015); over a year for the '306 patent (filed April 29, 2013, and issued July 8, 2014); and another year-plus for the '426 patent (filed May 8, 2015, and issued November 8, 2016).

88. When the '306 patents were challenged under *inter partes* review, Jazz affirmatively misled the PTAB. Jazz argued in response to IPR petitions that its label advised

[29] 2002 Xyrem label (attached as Exhibit 1), at 11; 2005 Xyrem label (attached as Exhibit 2), at 8.

[30] 2012 Xyrem Label (attached as Exhibit 3), at 2.

against, or "taught away," from co-administering sodium oxybate with any other CNS depressant (including valproate), at any dose.[31] Jazz relied on only the 2005 label for its "teaching away" argument to the PTAB, even while its 2012 label clarifications had retracted the very "should not be used" language on which Jazz relied. Jazz's own 2012 revision squarely contradicted its argument that the Xyrem label would have taught away from the claimed co-administration.

89. Jazz's actions before the PTAB were not just misleading, they violated the explicit disclosure requirements of IPR proceedings. Under 37 C.F.R. 42.51, "a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency." Instead of revealing the disclosure of the 2012 label pursuant to 37 C.F.R. 42.51, Jazz withheld it. Denying IPR institution, the PTAB relied first and foremost on Jazz's "teaching away" argument; an argument that was contradicted directly by the withheld 2012 label revision.[32]

G. ANDAs

90. On or about July 8, 2010, Roxane became the first generic manufacturer to file an ANDA requesting permission to market a generic version of Xyrem. It included in its application a Paragraph IV certification that all of Jazz's patents relating to Xyrem at the time were invalid, unenforceable, and/or would not be infringed by Roxane's generic.

91. Being the first-filer of an ANDA for generic Xyrem, Roxane was entitled to 180 days of generic exclusivity upon the approval of its ANDA.[33]

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[31] *See Amneal Pharms. LLC v. Jazz Pharms., Inc.*, IPR2016-00546, Paper 10 at 23-26 (PTAB May 6, 2016); *Par Pharm., Inc. et al. v. Jazz Pharms., Inc.*, IPR2016-0002, Paper 10 at 2, 29-30 (PTAB Jan. 15, 2016).

[32] *See Amneal Pharms. LLC v. Jazz Pharms., Inc.*, IPR2016-00546, Paper 12 at 11-12 (PTAB July 28, 2016); *Par Pharm., Inc. et al. v. Jazz Pharms., Inc.*,, IPR2016-0002, Paper 12 at 12. (PTAB Apr. 12, 2016).

[33] *See* FDA Sodium Oxybate ANDA Approval Letter dated January 17, 2017, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202090Orig1s000ltredt.pdf.

92. On or about October 14, 2010, Jazz received notice from Roxane of its ANDA, in compliance with the requirements under the Hatch-Waxman Act.

93. Between July 2014 and November 2017, additional ANDAs for generic sodium oxybate were filed by generic drug manufacturers Ranbaxy, Amneal, Par, Watson, Wockhardt, Lupin, Sun, Ohm, Mallinckrodt, and Ascent Pharmaceuticals, Inc.

94. The FDA approved Roxane's ANDA on January 17, 2017 and formally granted Roxane 180 days of generic exclusivity.[34]

H. The Xyrem Patent Litigations

95. On or about November 22, 2010, Jazz filed Case No. 10-cv-6108 in the District of New Jersey against Roxane, alleging Roxane's proposed generic would infringe the '889 patent, the '219 patent, the '730 patent, the '106 patent, and the '107 patent.

96. Over the next two years, Jazz filed additional complaints against Roxane alleging infringement of the '431 patent, the '506 patent, the '059 patent, the '650 patent, the '275 patent.[35] These cases were consolidated under Case No. 10-cv-6018 in the District of New Jersey.

97. On or about January 18, 2013, Jazz filed Case No. 13-cv-391 in the District of New Jersey against Amneal, alleging Amneal's proposed generic would infringe the '431 patent, 13-cv-391 the '889 patent, the '219 patent, the '506 patent, the '059 patent, the '650 patent, and the '275 patent.

98. Jazz filed additional suits against Amneal, Par, Ranbaxy, Watson, Wockhardt, Lupin, Sun, and Ohm, alleging the companies' respective ANDAs infringed one or more of its

[34] *Id.* at 2-3.

[35] *See* Case Nos. 11-cv-660 (D.N.J. Feb. 4, 2011); 11-cv-2523 (D.N.J. May 2, 2011); 12-cv-6761 (D.N.J. Oct 26, 2012); 12-cv-7459 (D.N.J. Dec. 5, 2012);

patents related to Xyrem.[36] The cases were consolidated under Case No. 13-cv-391 in the District of New Jersey. At issue in Case No. 13-cv-391 were the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, the '730 patent, the '106 patent, the '107 patent, the '059 patent, the '988 patent, the '182 patent, the '963 patent, the '306 patent, the '619 patent, and the '062 patent, the '302 patent, and the '426 patent.

99. On or about January 2, 2018, Jazz filed Case No. 18-cv-29 in the District of New Jersey against Mallinckrodt, alleging Mallinckrodt's proposed generic would infringe the '730, the '106 patent, the '107 patent, the '059 patent, the '988 patent, the '182 patent, the '963 patent, the '306 patent, the '302 patent, and the '426 patent.

I. The Unlawful and Anticompetitive Pay-for-Delay Settlements

100. To settle the patent litigations, Jazz entered into a series of anticompetitive reverse payment settlement agreements with the generic drug manufacturers.

101. Jazz settled its litigation with Defendant Roxane in April 2017 through an anticompetitive reverse payment settlement agreement. Contemporaneously with the execution of the Settlement Agreement,[37] Jazz and Roxane entered into a license agreement (the "License Agreement") and an authorized generic agreement (the "AG Agreement"), which are not available publicly. The term "Roxane Settlement" used hereinafter refers to the Settlement Agreement, License Agreement, and AG Agreement collectively.

[36] *See* District of New Jersey Case Nos. 13-cv-5450 (Sept. 12, 2013); 13-cv-7884 (Dec. 27, 2013); 14-cv-3235 (May 20, 2014); 14-cv-4467 (July 15, 2014); 14-cv-5139 (Aug. 15, 2014); 14-cv-6150 (Oct. 2, 2014); 14-cv-6151 (Oct. 2, 2014); 14-cv-7757 (Dec. 11, 2014); 15-cv-173 (Jan. 8, 2015); 15-cv-187 (Jan. 9, 2015); 15-cv-1043 (Feb. 6, 2015); 15-cv-3217 (May 7, 2015); 15-cv-4532 (June 26, 2015); 15-cv-5619 (July 17 2015); 15-cv-6548 (Sept. 1, 2015); 15-cv-6562 (Sept. 2, 2015); 15-cv-7580 (Oct. 19, 2015); 15-cv-8229 (Nov. 23, 2015); 16-cv-1505 (Mar. 17, 2016); 17-cv-1440 (Mar. 1, 2017); 18-cv-8267 (Apr. 24, 2018).

[37] *See* Settlement Agreement between Jazz and Roxane dated April 5, 2017, *available at* https://www.sec.gov/Archives/edgar/data/1232524/000123252417000134/jazzq22017ex101.htm.

102. The Roxane Settlement included a promise from Roxane not to market its generic version of Xyrem until July 1, 2023.

103. In consideration for its promise to delay launching its generic product, Roxane received, *inter alia*, (i) the exclusive right to sell an authorized generic (AG) between January 1, 2023 and July 1, 2023; (ii) a license to sell its own generic as of July 1, 2023; and (iii) a promise from Jazz not to grant additional licenses for other generic manufacturers to market their own generic products until December 31, 2025.

104. Upon information and belief, the value of the consideration Roxane received from Jazz as part of the Roxane Settlement was more than ten million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

105. On or about April 18, 2016, Jazz settled its litigation with Wockhardt. As part of the settlement, Jazz granted Wockhardt the right to manufacture, market, and sell its generic starting December 31, 2025.

106. On or about May 9, 2016, Jazz settled its litigation with Ranbaxy. As part of the settlement, Jazz granted Ranbaxy the right to manufacture, market, and sell its generic starting December 31, 2025.

107. On or about January 9, 2018, Jazz settled its litigation with Defendant Par through an anticompetitive reverse payment settlement agreement. As part of the settlement Jazz granted Par the right to sell an AG starting July 1, 2023, and the right to manufacture, market, and sell their own generic starting December 31, 2025. Upon information and belief, the value of the consideration Par received from Jazz as part of the settlement was more than ten million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

108. On or about March 30, 2018, Jazz settled its litigation with Watson. As part of the settlement, Jazz granted Watson the right to manufacture, market, and sell its generic starting December 31, 2025.

109. On or about June 4, 2018, Jazz settled its litigation with Mallinckrodt. As part of the settlement, Jazz granted Mallinckrodt the right to manufacture, market, and sell its generic starting December 31, 2025.

110. On or about June 12, 2018, Jazz settled its litigation with Defendant Lupin through an anticompetitive reverse payment settlement agreement. As part of the settlement Jazz granted Lupin the right to sell an AG starting July 1, 2023, and the right to manufacture, market, and sell their own generic starting December 31, 2025. Upon information and belief, the value of the consideration Lupin received from Jazz as part of the settlement was more than ten million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

111. On or about October 15, 2018, Jazz settled its litigation with Defendant Amneal through an anticompetitive reverse payment settlement agreement. As part of the settlement Jazz granted Amneal the right to sell an AG starting July 1, 2023, and the right to manufacture, market, and sell their own generic starting December 31, 2025. Upon information and belief, the value of the consideration Amneal received from Jazz as part of the settlement was more than ten million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

112. These unlawful anticompetitive settlements and any contemporaneous agreements are referred to collectively as the "Settlement Agreements."

113. By means of the Settlement Agreements, Defendants allocated the market for sodium oxybate in the United States according to the following schedule:

- Branded Xyrem will maintain its monopoly until December 31, 2022;
- On January 1, 2023, Jazz will introduce an AG, and profits from the AG will be shared with Roxane;
- On July 1, 2023, Jazz will introduce several more AGs, and profits from those AGs will be shared with Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt, respectively;
- Roxane may also launch its own generic on July 1, 2023;
- Finally, on December 31, 2025, Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt may launch their own generics.

114. As a result of the unlawful anticompetitive Settlement Agreements, Jazz will maintain complete control of the sodium oxybate market in the United States until at least July 1, 2023, and full generic competition will not occur until at least December 31, 2025.

VII. ANTICOMPETITIVE EFFECT

115. The anticompetitive scheme described above enabled Defendants to: (i) delay until January 1, 2023 the entry of any less-expensive generic versions of sodium oxybate products in the United States; (ii) restrict the market for sodium oxybate to branded Xyrem, Authorized Generics, and Roxane's generic until December 25, 2025; (iii) fix, raise, maintain, and/or stabilize the price of Xyrem and its generic equivalents.

116. But for the anticompetitive scheme, Roxane would have launched its generic as early as 2017; Amneal, Lupin, Par, Wockhardt, Ranbaxy, Watson, and Mallinckrodt would have followed after Roxane's 180-day exclusivity period; and full generic competition would have been achieved as early as 2018. As a result of Defendants' anticompetitive scheme, full generic competition will not be achieved until at least December 31, 2025.

117. Defendants' unlawful concerted action has: (i) delayed and prevented the sale of generic sodium oxybate in the United States; (ii) enabled Jazz to sell Xyrem at artificially inflated, supracompetitive prices; and (iii) caused Plaintiff and the Class to pay supracompetitive prices for Xyrem.

118. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

119. During the relevant period, Plaintiff and Class members purchased substantial amounts of Xyrem indirectly from Defendants at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and Class members were compelled to pay, and did pay, artificially inflated prices for Xyrem. Those prices were substantially greater than the prices that Plaintiff and Class members would have paid absent the illegal conduct alleged herein, because: (i) the price of Xyrem was artificially inflated by Defendants' illegal conduct, and (ii) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Xyrem, which they would have done had they had the opportunity.

120. As a consequence, Plaintiff and Class members have sustained substantial losses and damage to their business and/or property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charges passed through the chain of distribution to end-payors such as Plaintiff and Class members.

121. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Xyrem results in higher prices at every level below.[38]

122. The institutional structure of pricing and regulation in the pharmaceutical industry assures that overcharges at the higher level of distribution are passed on to End-Payors. Wholesalers and retailers passed on the inflated prices of Xyrem to Plaintiff and Class members. Further, the delayed entry of generic competition at the direct purchaser level similarly injured End-Payors who were equally denied the opportunity to purchase less expensive generic sodium oxybate.

123. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

124. Defendants' unlawful anticompetitive conduct alleged herein enabled them to indirectly charge End-Payors prices in excess of what they otherwise would have been able to charge absent their unlawful actions.

125. Prices of Xyrem were artificially inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

126. The supracompetitive prices Plaintiff and Class members paid are traceable to, and are the direct, proximate, and foreseeable result of, Defendants' anticompetitive conduct.

127. The overcharges Plaintiff and Class members paid are traceable to, and are the direct, proximate, and foreseeable result of, Defendants' supracompetitive pricing.

[38] Herbert Hovenkamp, Federal Antitrust Policy, The Law of Competition and its Practice 624 (1994). Professor Herbert Hovenkamp states that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level." *Id*

IX. EFFECT ON INTERSTATE COMMERCE

128. Defendants' anticompetitive conduct has substantially affected intrastate, interstate and foreign commerce.

129. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, it deprived retailers within each state of access to less expensive generic Xyrem that they could sell to End-Payors within each respective state. The delayed entry of generic Xyrem has directly affected and disrupted commerce for End-Payors within each state.

130. During the relevant time period, Xyrem was shipped into each state, and End-Payors paid for Xyrem in each state.

131. During the relevant time period, Defendants manufactured, promoted, distributed, and sold substantial amounts of Xyrem in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

132. During the relevant time period, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Xyrem.

X. MONOPOLY POWER AND MARKET DEFINITION

133. At all relevant times, Jazz had and maintained monopoly power in the market for Xyrem and its generic equivalents because it had the power to maintain the price of Xyrem at supracompetitive levels without losing sales so as to make the supracompetitive price unprofitable.

134. Direct proof exists that Jazz had monopoly power over the price of Xyrem. Such direct evidence includes, among other things, the abnormally-high price-cost margins enjoyed by Jazz and Jazz's ability to profitably raise and maintain the price of Xyrem well above competitive levels.

135. Manufacturers attempt to differentiate brand name drugs like Xyrem based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Xyrem. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. That different patients may respond differently to different drugs and even drugs within its same therapeutic class does not constrain the price of Xyrem.

136. Other drugs that are not AB-rated to Xyrem cannot be substituted automatically for Xyrem by pharmacists, do not exhibit substantial cross-price elasticity of demand with Xyrem, and thus are not economic substitutes for, nor reasonably interchangeable with, Xyrem.

137. Other products are not substitutes for Xyrem or its generic equivalents, and the existence of other products designed to treat narcolepsy have not significantly constrained Jazz's pricing of Xyrem. On information and belief, Jazz has never lowered the price of Xyrem in response to the pricing of other branded or generic drugs. In fact, Jazz has continuously raised the price of Xyrem.

138. Jazz needed to control only the sales of Xyrem, and no other products, in order to maintain the price of Xyrem profitably at supracompetitive prices. Only the market entry of a competing, generic version of Xyrem would render Jazz unable to profitably maintain its prices of Xyrem without losing substantial sales.

139. To the extent Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant market is Xyrem and generic equivalents (in all forms and dosage strengths). The relevant geographic market is the United States.

140. Jazz's anticompetitive reverse payments to the Generic Manufacturers demonstrate that Jazz enjoyed market and/or monopoly power with respect to sodium oxybate.

141. A small but significant non-transitory increase in price (SSNIP) above the competitive level for Xyrem by Jazz would not cause a loss of sales sufficient to make the price increase unprofitable. In fact, Jazz has increased the price of Xyrem in increments greater than the SSNIP level several times and has not suffered a corresponding decrease in sales.

142. At competitive price levels, Xyrem does not exhibit significant positive cross-price elasticity of demand with any product other than generic Xyrem.

143. Jazz, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections, and high costs of entry and expansion.

144. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination of lower cost generic Xyrem throughout the United States.

145. Jazz has maintained and exercised the power to exclude and restrict competition to Xyrem and its AB-rated generics.

146. At all relevant times, Jazz's market share in the relevant market was 100%, implying substantial monopoly power.

XI. CLASS ACTION ALLEGATIONS

147. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a), (b)(2) and (b)(3), as a representative of a class of End-Payor Purchasers (the "Class") defined as follows:

> All persons and entities in the United States and its territories that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Xyrem in any form, other than for resale, from June 17, 2017 through and

until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

The following persons and entities are excluded from the Class:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans;

c. All persons or entities who purchased Xyrem purposes of resale or directly from Defendants or their affiliates;

d. Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases of Xyrem were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. Pharmacy benefit managers; and

g. All judges assigned to this case and any members of their immediate families.

148. The Class is so numerous and widely geographically dispersed throughout the United States that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The identities of Class members will be readily ascertainable through business records kept in regular order. Plaintiff's claims are typical of Class members. Plaintiff and all Class members were damaged by the same wrongful conduct by Defendants. Defendants' anticompetitive conduct deprived the Class members of the benefits of competition from less-expensive generic sodium oxybate, causing them to pay artificially inflated, supracompetitive prices for the drug.

149. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are aligned with, and not antagonistic to, those of the other Class members.

150. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

151. Questions of law and fact common to Class members predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

152. Questions of law and fact common to the Class include:

a. Whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. Whether Defendants conspired to suppress generic competition to Xyrem;

c. Whether Defendants' challenged conduct suppressed generic competition to Xyrem;

d. Whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Jazz's power to exclude generic competition and charge supracompetitive prices for Xyrem and/or the per se illegal nature of the challenged conduct;

e. If a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing Jazz's monopoly power is, and whether Jazz had monopoly power in the relevant antitrust market;

f. Whether Jazz illegally obtained or maintained monopoly power in the relevant market;

g. Whether Defendants' actions were, on balance, unreasonable restraints of trade;

h. Whether Jazz's listings of certain Xyrem patents in the Orange Book was fraudulent;

i. Whether the Patent Settlements including large and unjustified payments in exchange for promises from the Generic Manufacturers to delay generic entry;

j. Whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

k. Whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Class; and

l. The quantum of overcharge damages paid by the Class in the aggregate.

153. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action

154. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Conspiracy and Combination in Restraint of Trade Under State Law

155. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

156. During the Class Period, Defendants engaged in a continuing contract, combination or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

157. During the Class Period, Defendants entered into an unlawful reverse payment agreements that restrained competition in the market for Xyrem and its generic equivalents.

158. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and its generic equivalents.

159. As a result of Defendants' unlawful conduct, Plaintiff and other similarly situated End-Payors in the Class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supra-competitive prices for Xyrem.

160. Defendants' conspiracy had the following effects, among others:

a. Delayed entry of generic sodium oxybate;

b. Extended Jazz's monopoly over the market for sodium oxybate;

c. Caused Jazz to make supra-competitive profits;

d. Raised and maintained the prices that Plaintiff and other Class members paid and are paying for Xyrem at supra-competitive levels.

161. Defendants engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, and/or stabilize prices of Xyrem.

162. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreements that outweighs its harmful effect on End-Payors and on competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

163. By engaging the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

c. Conn. Gen. Stat. § 35-26, *et seq.*, with respect to purchases of Xyrem in Connecticut by Class members and/or purchases by Connecticut residents.

d. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Xyrem in the District of Columbia by Class members and/or purchases by D.C. residents.

e. Haw. Rev. Stat §§ 480-1, *et seq.*, with respect to purchases of Xyrem in Hawaii by Class members and/or purchases by Hawaii residents.

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.4 *et seq.*, with respect to purchases of Xyrem in Iowa by Class members and/or purchases by Iowa residents.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Xyrem in Kansas by Class members and/or purchases by Kansas residents.

i. Md. Code, Com Law, Section 11-204, et seq. with respect to purchases in Maryland by Class members and/or purchases by Maryland residents.

j. Me. Stat. tit. 10 § 1101, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

k. Mich. Comp. Laws §§ 445.772, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Xyrem in Mississippi by Class members and/or purchases by Mississippi residents.

n. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of Xyrem in Nebraska by Class members and/or purchases by Nebraska residents.

o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

p. N.H. Rev. Stat. Ann. §§ 356:2, *et. seq*., with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Xyrem in New Mexico by Class members and/or purchases by New Mexico residents.

r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Xyrem in North Carolina by Class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Xyrem in North Dakota by Class members and/or purchases by North Dakota residents.

u. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to purchases of Xyrem in Puerto Rico by Class members and/or purchases by Puerto Rico residents.

w. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of Xyrem in South Dakota by Class members and/or purchases by South Dakota residents.

y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Xyrem in Tennessee by Class members and/or purchases by Tennessee residents.

z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. W.Va. Code §§ 47-18-43, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

SECOND CLAIM FOR RELIEF

Monopolization and Monopolistic Scheme Under State Law

164. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

165. As described above, at all relevant times, Jazz had monopoly power in the relevant market.

166. Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the relevant market by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not by providing a superior product, business acumen, or historical accident.

167. Defendants' conspiracy is ongoing.

168. Defendants knowingly and intentionally conspired to maintain and enhance each other's monopoly power in the relevant market, as described herein, injuring Plaintiff and the Class. Defendants accomplished this scheme by, *inter alia*,

a. Delaying entry of generic sodium oxybate;

b. Extending Jazz's monopoly over the market for sodium oxybate;

c. Causing Jazz to make supra-competitive profits;

d. Raising and maintaining the price so that Plaintiff and other Class members would pay supra-competitive prices for Xyrem; and

e. Otherwise conspiring to unlawfully monopolize the relevant market.

169. The goal, purpose, and effect of Defendants' scheme was also to maintain and extend Jazz's monopoly power with respect to Xyrem. Defendants' illegal scheme allowed Jazz to continue charging supra-competitive prices for Xyrem, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

170. There was and is no legitimate, non-pretextual, procompetitive justification for Defendants' conduct that outweighs its harmful effects. Even if there were some conceivable justification, the conduct is and was broader than necessary to achieve such a purpose.

171. As a result of Defendants' illegal conduct, Plaintiff and Class members were compelled to pay, and did pay, more than they would have paid for Xyrem absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Xyrem sooner than they did, and prices for Xyrem would have been and would be lower.

172. Had manufacturers of generic Xyrem entered the market and lawfully competed in a timely fashion, Plaintiff and other Class members would have substituted lower-priced generic Xyrem for the higher-priced brand-name Xyrem for some or all of their Xyrem requirements, and/or would have paid lower net prices on their remaining Xyrem purchases.

173. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Xyrem and they would have been able to market such versions successfully.

174. By engaging in the foregoing conduct, Defendants intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1403, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Cal. Bus. & Prof. Code §§ 16720, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

c. Conn. Gen. Stat. §§ 35-27, *et seq.*, with respect to purchases of Xyrem in Connecticut by Class members and/or purchases by Connecticut residents.

d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Xyrem in the District of Columbia by Class members and/or purchases by D.C. residents.

e. Haw. Rev. Stat. §§ 480-9, *et seq.*, with respect to purchases of Xyrem in Hawaii by Class members and/or purchases by Hawaii residents.

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Xyrem in Iowa by Class members and/or purchases by Iowa residents.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Xyrem in Kansas by Class members and/or purchases by Kansas residents.

i. Md. Code, Com Law, Section 11-204, et seq. with respect to purchases in Maryland by Class members and/or purchases by Maryland residents.

j. Me. Stat. tit. 10, § 1102, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

k. Mich. Comp. Laws §§ 445.773, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Xyrem in Mississippi by Class members and/or purchases by Mississippi residents.

n. Neb. Rev. Stat. §§ 59-802, *et seq.*, with respect to purchases of Xyrem in Nebraska by Class members and/or purchases by Nebraska residents.

o. N.H. Rev. Stat. Ann. §§ 356:3, et. seq., with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

p. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Xyrem in New Mexico by Class members and/or purchases by New Mexico residents.

r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Xyrem in North Carolina by Class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Xyrem in North Dakota by Class members and/or purchases by North Dakota residents.

u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

v. P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to purchases of Xyrem in Puerto Rico by Class members and/or purchases by Puerto Rico residents.

w. R.I. Gen. Laws §§ 6-36-7 *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Xyrem in South Dakota by Class members and/or purchases by South Dakota residents.

y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Xyrem in Tennessee by Class members and/or purchases by Tennessee residents.

z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. W. Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

bb. Wis. Stat. § 133.03, *et seq.*, of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

175. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members

were: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

176. Plaintiff and Class members accordingly seek damages and multiple damages as permitted by law.

THIRD CLAIM FOR RELIEF

Unfair Methods of Competition, and Unfair and Deceptive Acts, In Violation of State Consumer Protection Laws

177. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

178. Defendants engaged in unfair methods of competition and unfair, unconscionable, and/or deceptive acts or practices to wrongfully perpetuate their concerted conduct to restrain trade in the relevant market.

179. As a direct and proximate result of Defendants' unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Defendants' unlawful conduct.

180. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Class members could not reasonably have avoided injury from Defendants' wrongful conduct.

181. There was and is a gross disparity between the price that Plaintiff and the Class members paid for Xyrem and the value they received. Much more affordable generic Xyrem would have been and would be available, and prices for Xyrem would have been and would be far lower, but for Defendants' unfair, unconscionable, and deceptive conduct.

182. As a direct and proximate result of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were denied the opportunity to purchase generic Xyrem and forced to pay higher prices for Xyrem.

183. By engaging in such conduct, Defendants violated the following consumer protection laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1521, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases of Xyrem in Arkansas by Class members and/or purchases by Arkansas residents.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

d. Conn. Gen. Stat. §§ 42-110b, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by Connecticut residents.

e. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Xyrem in D.C. by Class members and/or purchases by D.C. residents.

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Xyrem in Florida by Class members and/or purchases by Florida residents.

g. Haw. Rev. Stat. §§ 481-1, *et seq.*, with respect to purchases of Xyrem in Hawaii by Class members and/or purchases by Hawaii residents.

h. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Xyrem in Idaho by Class members and/or purchases by Idaho residents.

i. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

j. Kan. Stat. Ann. §§ 50-623, *et seq.*, with respect to purchases of Xyrem in Kansas by Class members and/or purchases by Kansas residents.

k. Me. Stat. tit. 5, §§ 207, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

l. Mass. Gen. Laws ch. 93A, §§ 1 *et seq.*, with respect to purchases of Xyrem in Massachusetts by Class members and/or purchases by Massachusetts residents.

m. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

n. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

o. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of Xyrem in Missouri by Class members and/or purchases by Missouri residents.

p. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Xyrem in Nebraska by Class members and/or purchases by Nebraska residents.

q. Nev. Rev. Stat. Ann. §§ 598.0903, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

r. N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*, with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

s. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of Xyrem in New Mexico by Class members and/or purchases by New Mexico residents.

t. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

u. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Xyrem in North Carolina by Class members and/or purchases by North Carolina residents.

v. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

w. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws §§ 37-24-6, *et seq.*, with respect to purchases of Xyrem in South Dakota by Class members and/or purchases by South Dakota residents.

y. Tenn. Code Ann. §§ 47-18-101, *et seq.*, with respect to purchases of Xyrem in Tennessee by Class members and/or purchases by Tennessee residents.

z. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. Vt. Stat Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Xyrem in Vermont by Class members and/or purchases by Vermont residents.

bb. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

cc. Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

184. Plaintiff and Class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct. Their injury consists of paying higher prices for Xyrem than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

185. On behalf of itself and the Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

FOURTH CLAIM FOR RELIEF

Unjust Enrichment

186. Plaintiff incorporates the above paragraphs by reference.

187. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

188. Defendants have reaped and retained substantially higher profits due to their unlawful scheme.

189. Plaintiff and Class members have conferred and continue to confer an economic benefit upon Defendants in the form of profits resulting from the unlawful overcharges from Xyrem sales described herein, to the economic detriment of Plaintiff and Class members.

190. Defendants' financial gain from their unlawful conduct is traceable to overpayments for Xyrem by Plaintiff and Class members.

191. Plaintiff and Class members have no adequate remedy at law.

192. It would be futile for Plaintiff and Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Xyrem, as those intermediaries are not liable and would not compensate Plaintiff and Class members for Defendants' unlawful conduct.

193. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff and the Class members for Xyrem sold by Defendants during the Class Period.

194. The financial benefits Defendants derived from overcharging Plaintiff and Class members for Xyrem is a direct and proximate result of Defendants' unlawful practices described herein.

195. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

196. It would be wrong and inequitable, under unjust enrichment principles under the laws of each state in the United States as well as the District of Columbia, except for Indiana and Ohio, for Defendants to be permitted to retain any of the overcharges that Plaintiff and Class members paid for Xyrem that were derived from Defendants' unlawful practices described herein.

197. Defendants are aware of and appreciate the benefits that Plaintiff and Class members have bestowed upon them.

198. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Class members.

199. Plaintiff and Class members are entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which Plaintiff and Class members may make claims on a pro rata basis.

FIFTH CLAIM FOR RELIEF

Declaratory and Injunctive Relief Under Sections 1 and 2 of the Sherman Act and Section 16 of the Clayton Act (15 U.S.C. §§ 1-2, 26)

200. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

201. Plaintiff seeks declaratory and injunctive relief under the federal antitrust laws.

202. Plaintiff's allegations described herein constitute violations of Sections 1 and 2 of the Sherman Act.

203. Defendants effectuated a scheme to restrain trade and monopolize a market.

204. There is and was no legitimate, non-pretextual, pro-competitive business justification for Defendants' conduct that outweighs its harmful effect.

205. As a direct and proximate result of Defendants' anticompetitive scheme, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

206. The goal, purpose and/or effect of the scheme was to prevent and/or delay competition to continue charging supra-competitive prices for Xyrem without a substantial loss of sales.

207. Plaintiff and the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Xyrem than they would have paid in the absence of those violations. These injuries will continue unless halted.

208. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct constitutes a violation of Sections 1 and 2 of the Sherman Act.

209. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct the anticompetitive effects caused by Defendants' unlawful conduct.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and appoint the Plaintiff as the named representative of the Class;

b. Grant injunctive relief that restores Defendants' incentives to compete in the relevant market;

c. Award Plaintiff and the Class damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

d. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

e. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

f. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees, as provided by law; and

g. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIV. JURY DEMAND

210. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: July 31, 2020

Respectfully submitted,

MOTLEY RICE LLC

By: */s/ Michael M. Buchman*

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